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Chip implants linked to animal tumors

By **TODD LEWAN**

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A VeriChip microchip held in pair of tweezers.
(AP)

When the U.S. Food and Drug Administration approved implanting microchips in humans, the manufacturer said it would save lives, letting doctors scan the tiny transponders to access patients' medical records almost instantly. The FDA found "reasonable assurance" the device was safe, and a sub-agency even called it one of 2005's top "innovative technologies."

But neither the company nor the regulators publicly mentioned this: A series of veterinary and toxicology studies, dating to the

mid-1990s, stated that chip implants had "induced" malignant tumors in some lab mice and rats.

"The transponders were the cause of the tumors," said Keith Johnson, a retired toxicologic pathologist, explaining in a phone interview the findings of a 1996 study he led at the Dow Chemical Co. in Midland, Mich.

Leading cancer specialists reviewed the research for The Associated Press and, while cautioning that animal test results do not necessarily apply to humans, said the findings troubled them. Some said they would not allow family members to receive implants, and all urged further research before the glass-encased transponders are widely implanted in people.

To date, about 2,000 of the so-called radio frequency identification, or RFID, devices have been implanted in humans worldwide, according to VeriChip Corp. The company, which sees a target market of 45 million Americans for its medical monitoring chips, insists the devices are safe, as does its parent company, Applied Digital Solutions, of Delray Beach, Fla.

"We stand by our implantable products which have been approved by the FDA and/or other U.S. regulatory authorities," Scott Silverman, VeriChip Corp. chairman and chief executive officer, said in a written response to AP questions.

The company was "not aware of any studies that have resulted in malignant tumors in laboratory rats, mice and certainly not dogs or cats," but he added that millions of domestic pets have been implanted with microchips, without reports of significant problems.

"In fact, for more than 15 years we have used our encapsulated glass transponders with FDA approved anti-migration caps and received no complaints regarding malignant tumors caused by our product."

The FDA also stands by its approval of the technology.

Did the agency know of the tumor findings before approving the chip implants? The FDA declined repeated AP requests to specify what studies it reviewed.

The FDA is overseen by the Department of Health and Human Services, which, at the time of VeriChip's approval, was headed by Tommy Thompson. Two weeks after the device's approval took effect on Jan. 10, 2005, Thompson left his Cabinet post, and within five months was a board member of VeriChip Corp. and Applied Digital Solutions. He was compensated in cash and stock options.

Thompson, until recently a candidate for the 2008 Republican presidential nomination, says he had no personal relationship with the company as the VeriChip was being evaluated, nor did he play any role in FDA's approval process of the RFID tag.

"I didn't even know VeriChip before I stepped down from the Department of Health and Human Services," he said in a telephone interview.

Also making no mention of the findings on animal tumors was a June report by the ethics committee of the American Medical Association, which touted the benefits of implantable RFID devices.

Had committee members reviewed the literature on cancer in chipped animals?

No, said Dr. Steven Stack, an AMA board member with knowledge of the committee's review.

Was the AMA aware of the studies?

No, he said.

Published in veterinary and toxicology journals between 1996 and 2006, the studies found that lab mice and rats injected with microchips sometimes developed subcutaneous "sarcomas" - malignant tumors, most of them encasing the implants.

- A 1998 study in Ridgefield, Conn., of 177 mice reported cancer incidence to be slightly higher than 10 percent - a result the researchers described as "surprising."

- A 2006 study in France detected tumors in 4.1 percent of 1,260 microchipped mice. This was one of six studies in which the scientists did not set out to find microchip-induced cancer but noticed the growths incidentally. They were testing compounds on behalf of chemical and pharmaceutical companies; but they ruled out the compounds as the tumors' cause. Because researchers only noted the most obvious tumors, the French study said, "These incidences may therefore slightly underestimate the true occurrence" of cancer.

- In 1997, a study in Germany found cancers in 1 percent of 4,279 chipped mice. The tumors "are clearly due to the implanted microchips," the authors wrote.

Caveats accompanied the findings. "Blind leaps from the detection of tumors to the prediction of human health risk should be avoided," one study cautioned. Also, because none of the studies had a control group of animals that did not get chips, the normal rate of tumors cannot be determined and compared to the rate with chips implanted.

Still, after reviewing the research, specialists at some pre-eminent cancer institutions said the findings raised red flags.

"There's no way in the world, having read this information, that I would have one of those chips implanted in my skin, or in one of my family members," said Dr. Robert Benezra, head of the Cancer Biology Genetics Program at the Memorial Sloan-Kettering Cancer Center in New York.

Before microchips are implanted on a large scale in humans, he said, testing should be done on larger animals, such as dogs or monkeys. "I mean, these are bad diseases. They are life-threatening. And given the preliminary animal data, it looks to me that there's definitely cause for concern."

Dr. George Demetri, director of the Center for Sarcoma and Bone Oncology at the Dana-Farber Cancer Institute in Boston, agreed. Even though the tumor incidences were "reasonably small," in his view, the research underscored "certainly real risks" in RFID implants.

In humans, sarcomas, which strike connective tissues, can range from the highly curable to "tumors that are incredibly aggressive and can kill people in three to six months," he said.

At the Jackson Laboratory in Maine, a leader in mouse genetics research and the initiation of cancer, Dr. Oded Foreman, a forensic pathologist, also reviewed the studies at the AP's

request.

At first he was skeptical, suggesting that chemicals administered in some of the studies could have caused the cancers and skewed the results. But he took a different view after seeing that control mice, which received no chemicals, also developed the cancers. "That might be a little hint that something real is happening here," he said. He, too, recommended further study, using mice, dogs or non-human primates.

Dr. Cheryl London, a veterinarian oncologist at Ohio State University, noted: "It's much easier to cause cancer in mice than it is in people. So it may be that what you're seeing in mice represents an exaggerated phenomenon of what may occur in people."

Tens of thousands of dogs have been chipped, she said, and veterinary pathologists haven't reported outbreaks of related sarcomas in the area of the neck, where canine implants are often done. (Published reports detailing malignant tumors in two chipped dogs turned up in AP's four-month examination of research on chips and health. In one dog, the researchers said cancer appeared linked to the presence of the embedded chip; in the other, the cancer's cause was uncertain.)

Nonetheless, London saw a need for a 20-year study of chipped canines "to see if you have a biological effect." Dr. Chand Khanna, a veterinary oncologist at the National Cancer Institute, also backed such a study, saying current evidence "does suggest some reason to be concerned about tumor formations."

Meanwhile, the animal study findings should be disclosed to anyone considering a chip implant, the cancer specialists agreed.

To date, however, that hasn't happened.

The product that VeriChip Corp. won approval for use in humans is an electronic capsule the size of two grains of rice. Generally, it is implanted with a syringe into an anesthetized portion of the upper arm.

When prompted by an electromagnetic scanner, the chip transmits a unique code. With the code, hospital staff can go on the Internet and access a patient's medical profile that is maintained in a database by VeriChip Corp. for an annual fee.

VeriChip Corp., whose parent company has been marketing radio tags for animals for more than a decade, sees an initial market of diabetics and people with heart conditions or Alzheimer's disease, according to a Securities and Exchange Commission filing.

The company is spending millions to assemble a national network of hospitals equipped to scan chipped patients.

But in its SEC filings, product labels and press releases, VeriChip Corp. has not mentioned the existence of research linking embedded transponders to tumors in test animals.

When the FDA approved the device, it noted some Verichip risks: The capsules could migrate around the body, making them difficult to extract; they might interfere with defibrillators, or be incompatible with MRI scans, causing burns. While also warning that the chips could cause "adverse tissue reaction," FDA made no reference to malignant growths in animal studies.

Did the agency review literature on microchip implants and animal cancer?

Dr. Katherine Albrecht, a privacy advocate and RFID expert, asked shortly after VeriChip's approval what evidence the agency had reviewed. When FDA declined to provide information, she filed a Freedom of Information Act request. More than a year later, she received a letter stating there were no documents matching her request.

"The public relies on the FDA to evaluate all the data and make sure the devices it approves are safe," she says, "but if they're not doing that, who's covering our backs?"

Late last year, Albrecht unearthed at the Harvard medical library three studies noting cancerous tumors in some chipped mice and rats, plus a reference in another study to a chipped dog with a tumor. She forwarded them to the AP, which subsequently found three additional mice studies with similar findings, plus another report of a chipped dog with a tumor.

Asked if it had taken these studies into account, the FDA said VeriChip documents were being kept confidential to protect trade secrets. After AP filed a FOIA request, the FDA made

available for a phone interview Anthony Watson, who was in charge of the VeriChip approval process.

"At the time we reviewed this, I don't remember seeing anything like that," he said of animal studies linking microchips to cancer. A literature search "didn't turn up anything that would be of concern."

In general, Watson said, companies are expected to provide safety-and-effectiveness data during the approval process, "even if it's adverse information."

Watson added: "The few articles from the literature that did discuss adverse tissue reactions similar to those in the articles you provided, describe the responses as foreign body reactions that are typical of other implantable devices. The balance of the data provided in the submission supported approval of the device."

Another implantable device could be a pacemaker, and indeed, tumors have in some cases attached to foreign bodies inside humans. But Dr. Neil Lipman, director of the Research Animal Resource Center at Memorial Sloan-Kettering, said it's not the same. The microchip isn't like a pacemaker that's vital to keeping someone alive, he added, "so at this stage, the payoff doesn't justify the risks."

Silverman, VeriChip Corp.'s chief executive, disagreed. "Each month pet microchips reunite over 8,000 dogs and cats with their owners," he said. "We believe the VeriMed Patient Identification System will provide similar positive benefits for at-risk patients who are unable to communicate for themselves in an emergency."

And what of former HHS secretary Thompson?

When asked what role, if any, he played in VeriChip's approval, Thompson replied: "I had nothing to do with it. And if you look back at my record, you will find that there has never been any improprieties whatsoever."

FDA's Watson said: "I have no recollection of him being involved in it at all." VeriChip Corp. declined comment.

Thompson vigorously campaigned for electronic medical records and healthcare technology both as governor of Wisconsin and at HHS. While in President Bush's Cabinet, he formed a "medical innovation" task force that worked to partner FDA with companies developing medical information technologies.

At a "Medical Innovation Summit" on Oct. 20, 2004, Lester Crawford, the FDA's acting commissioner, thanked the secretary for getting the agency "deeply involved in the use of new information technology to help prevent medication error." One notable example he cited: "the implantable chips and scanners of the VeriChip system our agency approved last week."

After leaving the Cabinet and joining the company board, Thompson received options on 166,667 shares of VeriChip Corp. stock, and options on an additional 100,000 shares of stock from its parent company, Applied Digital Solutions, according to SEC records. He also received \$40,000 in cash in 2005 and again in 2006, the filings show.

The Project on Government Oversight called Thompson's actions "unacceptable" even though they did not violate what the independent watchdog group calls weak conflict-of-interest laws.

"A decade ago, people would be embarrassed to cash in on their government connections. But now it's like the Wild West," said the group's executive director, Danielle Brian.

Thompson is a partner at Akin Gump Strauss Hauer & Feld LLP, a Washington law firm that was paid \$1.2 million for legal services it provided the chip maker in 2005 and 2006, according to SEC filings.

He stepped down as a VeriChip Corp. director in March to seek the GOP presidential nomination, and records show that the company gave his campaign \$7,400 before he bowed out of the race in August.

In a TV interview while still on the board, Thompson was explaining the benefits - and the ease - of being chipped when an interviewer interrupted:

"I'm sorry, sir. Did you just say you would get one implanted in your arm?"

"Absolutely," Thompson replied. "Without a doubt."

"No concerns at all?"

"No."

But to date, Thompson has yet to be chipped himself.

On the Web:

<http://www.verichipcorp.com>

<http://www.antichips.com>

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